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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,049	12/12/2003	Kyogo Itoh	Q-78382	2555

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
GODDARD, LAURA B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,049	ITOH ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 27, 30, 31, drawn to an isolated peptide, pharmaceutical composition comprising the peptide(s), a cancer vaccine comprising the peptide(s), and kit, classified in class 530, subclass 350.

Additionally, Applicants must elect a single peptide or polypeptide sequence SEQ ID NO:

(claims 1, 3, 4, 7, 8, 9) SEQ ID NOs:1-213, 358-381, 388-408,

(claims 2, 5, 6, 7, 8, 9) SEQ ID NOs: 214-288, 356, 357, 385-387

as each sequence presents a structurally and functionally *distinct* invention not a species.

II. Claims 10, 34, 35, drawn to a method for inducing a cytotoxic T lymphocyte comprising contacting peripheral blood mononuclear cells with one or more of peptides, classified in class 514, subclass 2.

Additionally, Applicants must elect a single peptide or polypeptide sequence SEQ ID NOs: 1-213, 358-381, 388-408, 214-288, 356, 357, 385-387, **as each sequence presents a structurally and functionally *distinct* invention not a species.**

III. Claims 11-19, 27, 30, 31, drawn to an isolated polynucleotide, vector comprising the polynucleotide, and transformant transformed with the

vector, a pharmaceutical composition comprising the polynucleotide, and kit, classified in class 536, subclass 23.1.

Additionally, Applicants must elect a <u>single</u> polynucleotide sequence SEQ ID NO:

(claim 11) a polynucleotide encoding SEQ ID NOs: 1-288, 356-381, 385-408

(claims 12, 13) polynucleotide SEQ ID NOs: 289-355, 382-384.

as each sequence presents a structurally and functionally *distinct* invention not a species.

IV. Claims 20, 27, 30, 31, drawn to an antibody, a pharmaceutical composition comprising the antibody, and kit, classified in class 530, subclass 387.1.

Additionally, Applicants must elect a <u>single</u> peptide or polypeptide sequence SEQ ID NOs: 1-213, 358-381, 388-408, 214-288, 356, 357, 385-387, **as each sequence presents a structurally and functionally *distinct* invention not a species.**

V. Claim 21, drawn to a method for screening for a compound that enhances recognition of a peptide by an HLA-A2-restricted or HLA-A26-restricted cytotoxic T lymphocyte comprising **contacting said peptide** with a compound, classified in class 435, subclass 7.1.

Additionally, Applicants must elect a single peptide or polypeptide sequence:

(claim 4) SEQ ID NOs:1-213, 358-381, 388-408

(claim 6) SEQ ID NOs: 214-288, 356, 357, 385-387

as each sequence presents a structurally and functionally *distinct* invention not a species.

VI. Claim 22, drawn to a method for screening for a compound that enhances recognition of a peptide by an HLA-A2-restricted or HLA-A26-restricted cytotoxic T lymphocyte comprising **contacting HLA-A2+ cells or HLA-A26+ cells which have been pulsed with said peptide** with said cytotoxic T lymphocytes in the presence or absence of a compound, classified in class 435, subclass 7.2.

Additionally, Applicants must elect a single peptide or polypeptide sequence: (claim 4) SEQ ID NOs:1-213, 358-381, 388-408

as each sequence presents a structurally and functionally *distinct* invention not a species.

VII. Claim 23, drawn to a method for screening for a compound that enhances recognition of a peptide by an HLA-A2-restricted or HLA-A26-restricted cytotoxic T lymphocyte comprising **contacting HLA-A2+ cells or HLA-A26+ cells into which a polynucleotide has been transfected** with said

cytotoxic T lymphocytes in the presence or absence of a compound, classified in class 435, subclasses 7.2, 69.1.

Additionally, Applicants must elect a <u>single</u> peptide or polypeptide sequence: (claim 4) SEQ ID NOs:1-213, 358-381, 388-408

<u>and</u> single polynucleotide that encodes for the elected peptide or polypeptide: SEQ ID NOs: 289-355, 382-384

as each sequence presents a structurally and functionally *distinct* invention not a species.

VIII. Claims 24, 25, drawn to a compound that **enhances recognition of a peptide** by an HLA-A2-restricted or HLA-A26-restricted cytotoxic T lymphocyte, classified in class 424, subclass 278.1.

Additionally, Applicants must elect a <u>single</u> peptide or polypeptide sequence:

(claim 4) SEQ ID NOs:1-213, 358-381, 388-408

(claim 6) SEQ ID NOs: 214-288, 356, 357, 385-387

as each sequence presents a structurally and functionally *distinct* invention not a species.

Claim 25 will be examined as drawn to the elected peptide or polypeptide.

IX. Claim 26, drawn to a compound that **enhances the expression of a polynucleotide**, classified in class 424, subclass 278.1.

Additionally, Applicants must elect a single polynucleotide sequence SEQ ID NO:

a polynucleotide encoding SEQ ID NO: 1-288, 356-381, 385-408

a polynucleotide SEQ ID NO: 289-355, 382-384.

as each sequence presents a structurally and functionally *distinct* invention not a species.

X. Claims 28 in part, 29, 36 in part , drawn to a method for measuring quantitatively or qualitatively a peptide or polypeptide, classified in class 435, subclass 7.1.

Additionally, Applicants must elect a single peptide or polypeptide sequence SEQ ID NOs: 1-213, 358-381, 388-408, 214-288, 356, 357, 385-387,

as each sequence presents a structurally and functionally *distinct* invention not a species.

XI. Claims 28 in part, 29, 36 in part, drawn to a method for measuring quantitatively or qualitatively a polynucleotide, classified in class 435, subclass 6.

Additionally, Applicants must elect a single polynucleotide sequence SEQ ID NO:

a polynucleotide encoding SEQ ID NO: 1-288, 356-381, 385-408

a polynucleotide SEQ ID NO: 289-355, 382-384.

as each sequence presents a structurally and functionally *distinct* invention not a species.

XII. Claims 32, 33, drawn to a method for treating cancer comprising administering a cancer vaccine *in vivo*, classified in class 514, subclass 2. **Additionally, Applicants must elect a single peptide or polypeptide sequence SEQ ID NOs:** 1-213, 358-381, 388-408, 214-288, 356, 357, 385-387, **as each sequence presents a structurally and functionally *distinct* invention not a species.**

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group III is related to the protein of Group I by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of Groups III and I together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups III and I have a separate

status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the claims include several distinct SEQ ID NOs and complements thereof. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above: furthermore, a search of the nucleic acid molecules of Group III would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of Group I. As such, it would be burdensome to search the inventions of Groups III and I.

The polypeptide of Group I and the antibody of Group IV are patentably distinct for the following reasons:

While the inventions of both Group I and Group IV are polypeptides, in this instance the polypeptides of Group I represent various proposed cell cycling protein, whereas the polypeptide of Group IV encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily

determining regions (CDR) that function to bind an epitope. Thus the polypeptides of Group I and the antibodies of Group IV are structurally distinct molecules; any relationship between a polypeptide of Group I and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Searching the inventions of Group I and Group IV would impose a serious search burden. The inventions have separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group IV. Furthermore, antibodies which bind to an epitope of a polypeptide of Group I may be known even if a polypeptide of Group I is novel. In addition, the technical literature search for the polypeptides of Group I and the antibody of Group IV are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of Group III and the antibody of Group IV are patentably distinct for the following reasons:

The antibody of Group IV includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining

regions (CDRs). Polypeptides, such as the antibody of Group IV which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group III will not encode an antibody of Group IV, and the antibody of Group IV cannot be encoded by a polynucleotide of Group III. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group III and Group IV would impose a serious search burden since a search of the polynucleotides of Group III would not be used to determine the patentability of any antibody of Group IV, and vice-versa.

The product of Group VIII is not related to the product of Groups I, III, IV, and IX. The product of Group IX is not related to the products of Group I, III, IV and VIII.

Inventions I and II, V-VII, X-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide or polypeptide of Group I can be used to produce antibodies or for affinity chromatography.

Inventions III and VII, IX, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group III can be used for hybridization assays or for affinity chromatography.

The inventions of Groups II, V-VII, and X-XII are materially distinct methods which differ at least in objectives, method steps and reagents. For example, Group II is drawn to a method for inducing a cytotoxic T lymphocyte comprising contacting peripheral blood mononuclear cells with a peptide. Groups V-VII are drawn to the different objective of a method for screening for a compound that enhances recognition of a peptide by a cytotoxic T lymphocyte wherein each Group utilizes structurally and functionally different reagents and method steps of achieving the objective. Groups X and XI are drawn to the different objective of quantitatively or qualitatively measuring structurally and functionally different molecules which require different method steps and reagents. Groups XII is drawn to the different objective of treating cancer comprising administering a cancer vaccine *in vivo*. Each of the groups employs chemically distinct reagents to accomplish different objectives that comprise different method steps. Searching all of the groups with all of the different objectives, method steps, and reagents would invoke a high burden of search.

The product of Group III is not used in the methods of Groups II, V, VI, X, and XII. The product of Group IV is not used in the methods of Groups II, V-VII, and X-XII.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

12/22/08